

BIOTECHNOLOGY (PIPS) RULE

ISSUE SUMMARY:

EPA has proposed the [Pesticides; Exemptions of Certain Plant-Incorporated Protectants \(PIPs\) Derived from Newer Technologies](#) rule that will streamline the regulation of certain plant-incorporated protectants (PIPs) that pose no risks of concern to humans or the environment. This action was published on EPA's website on September 1, 2020 and is now available for public comment through December 8, 2020. This important regulation is consistent with the directive contained in the June 2019 [Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products](#).

UPCOMING MILESTONES:

- Conclusion of public comment period – December 8, 2020
- EPA review of public comments
- Drafting, review, and publication of the final rule

BACKGROUND:

- EPA, USDA, and FDA have shared responsibility for regulating agricultural biotechnology. EPA regulates pesticides created through biotechnology as a part of its jurisdiction over all pesticides sold or distributed in the United States. As such, EPA has developed rules to facilitate the regulation of genetically engineered biological pesticides, which present distinctive characteristics relative to more conventional pesticides.
- EPA's authority to regulate pesticides and pesticide chemical residues created through biotechnology falls under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA).
- EPA's relevant FIFRA regulations focus on pesticides that are produced and used in plants. They define a "plant incorporated protectant," or "PIP," as a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant or produce thereof.
- The June 2019 Executive Order 13874, *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* directs EPA to use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation to the extent consistent with law and the Executive Order.
- EPA proposed a rule in the Federal Register to streamline the regulation of certain plant-incorporated protectants (PIPs) on October 9, 2020.
- EPA's proposed rule would exempt certain plant-incorporated protectant products – or PIPs – that meet the proposed regulatory criteria from regulation under FIFRA and FFDCA due to their low risk, i.e., PIPs that are developed through biotechnology that are equivalent to the low-risk PIPs developed through conventional breeding that are already exempted.
- Under the proposed exemption, EPA would require developers of PIPs to submit either a self-determination

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letter or a request for EPA confirmation that their PIP meets the criteria for exemption. For increased flexibility in bringing PIPs to market, a developer could also submit both.

KEY EXTERNAL STAKEHOLDERS:

☒ Congress ☒ Industry ☒ States ☐ Tribes ☒ Media ☒ Other Federal Agency
☒ NGO ☐ Local Government ☐ Other: _____

Stakeholder interest has focused on support for regulatory relief.

MOVING FORWARD:

Once the comment period on the proposed rule concludes, OCSPP plans to review the comments and develop a final rule for clearance and publication. The fall Regulatory Agenda, when published, will list the target date for the final rule as July 2021.

LEAD OFFICE/REGION: OCSPP

OTHER KEY OFFICES/REGIONS: (OGC, OECA, OP)